



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 721

[EPA-HQ-OPPT-2022-0462; FRL-10183-02-OCSPP]

RIN 2070-AB27

### Significant New Use Rules on Certain Chemical Substances (22-2.5e)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances that were the subject of premanufacture notices (PMNs) and are also subject to Orders issued by EPA pursuant to TSCA. The SNURs require persons who intend to manufacture (defined by statute to include import) or process any of these chemical substances for an activity that is proposed as a significant new use by this rule to notify EPA at least 90 days before commencing that activity. The required notification initiates EPA's evaluation of the use, under the conditions of use for that chemical substance, within the applicable review period. Persons may not commence manufacture or processing for the significant new use until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required by that determination.

**DATES:** Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2022-0462, through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at

<https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4163; email address: [wysong.william@epa.gov](mailto:wysong.william@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this action apply to me?*

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this proposed rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import provisions promulgated at 19 CFR 12.118 through 12.127 and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and Orders under TSCA, which would include the SNUR requirements should these proposed rules be finalized. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or

after [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

*B. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

## **II. Background**

*A. What action is the Agency taking?*

EPA is proposing these SNURs under TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) for certain chemical substances that were the subject of PMNs. These proposed SNURs would require persons to notify EPA at least 90 days before commencing the manufacture or processing of any of these chemical substances for an activity proposed as a significant new use. Receipt of such notices would allow EPA to assess risks and, if appropriate, to regulate the significant new use before it may occur.

The docket for these proposed SNURs, identified as docket ID number EPA-HQ-OPPT-2022-0462, includes information considered by the Agency in developing these proposed SNURs.

*B. What is the Agency's authority for taking this action?*

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four TSCA section 5(a)(2) factors listed in Unit III.

*C. Applicability of General Provisions*

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to these SNURs must comply with the same significant new use notice (SNUN) requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). These requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN and before the manufacture or processing for the significant new use can commence, EPA must either determine that the use is not likely to present an unreasonable risk of injury under the conditions of use for the chemical substance or take such regulatory action as is associated with an alternative determination. If EPA determines that the use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the *Federal Register*, a statement of EPA’s findings.

**III. Significant New Use Determination**

TSCA section 5(a)(2) states that EPA’s determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.

- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances, potential human exposures and environmental releases that may be associated with possible uses of these chemical substances, in the context of the four TSCA section 5(a)(2) factors listed in this unit.

The proposed rules include PMN substances that are subject to Orders issued under TSCA section 5(e)(1)(A), as required by the determinations made under TSCA section 5(a)(3)(B). The TSCA Orders require protective measures to limit exposures or otherwise mitigate the potential unreasonable risk. The proposed SNURs identify significant new uses as any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).

Where EPA determined that the PMN substance may present an unreasonable risk of injury to human health via inhalation exposure, the underlying TSCA Order usually requires that potentially exposed employees wear specified respirators unless actual measurements of the workplace air show that air-borne concentrations of the PMN substance are below a New Chemical Exposure Limit (NCEL), and includes requirements addressing performance criteria for sampling and analytical methods, periodic monitoring, respiratory protection, and recordkeeping. No comparable NCEL provisions currently exist in 40 CFR part 721, subpart B, for SNURs. Therefore, for these cases, the individual SNURs in 40 CFR part 721, subpart E, will state that persons subject to the SNUR who wish to pursue NCELs as an alternative to the 40 CFR 721.63 respirator requirements may request to do so under 40 CFR 721.30. EPA expects

that persons whose 40 CFR 721.30 requests to use the NCEs approach for SNURs that are approved by EPA will be required to comply with NCEs provisions that are comparable to those contained in the corresponding TSCA Order for the same chemical substance.

#### **IV. Rationale and Objectives of the Proposed Rule**

##### *A. Rationale*

During review of the PMNs submitted for the chemical substances that are the subject to these proposed SNURs, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of the chemical substances. The basis for such findings is outlined in Unit V. Based on these findings, TSCA section 5(e) Orders requiring the use of appropriate exposure controls were negotiated with the PMN submitters. As a general matter, EPA believes it is necessary to follow the TSCA Orders with a SNUR that identifies the absence of those protective measures as significant new uses to ensure that all manufacturers and processors – not just the original submitter – are held to the same standard.

##### *B. Objectives*

EPA is proposing these SNURs for specific chemical substances which have undergone premanufacture review because the Agency wants:

- To identify as significant new uses any manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the restrictions imposed by the underlying TSCA Orders, consistent with TSCA section 5(f)(4).
- To have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- To be able to either determine that the prospective manufacture or processing is not likely to present an unreasonable risk, or to take necessary regulatory action associated with any other determination before the described significant new use of the chemical substance occurs.

## V. Substances Subject to this Proposed Rule

EPA is proposing significant new use and recordkeeping requirements for certain chemical substances in 40 CFR part 721, subpart E. In this unit, EPA provides the following information for each chemical substance that is identified in this unit as subject to this proposed rule:

- PMN number (the proposed CFR citation assigned in the regulatory text section of the proposed rule).
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Effective date of and basis for the TSCA Section 5(e) Order.
- Potentially Useful Information.

The chemicals subject to these proposed SNURs are as follows:

**PMN Number: P-16-349 (40 CFR 721.11752).**

*Chemical Name:* Quaternary ammonium salt of polyisobutene succinic acid (generic).

*CAS Number:* Not available.

*Effective date of modification of TSCA Order:* October 18, 2021.

*Basis for TSCA Order modification:* The PMN states that the generic (non-confidential) use of the substance will be as a fuel additive. On November 30, 2018, EPA issued a Consent Order regarding premanufacture notice P-16-349. The Order was issued under TSCA sections 5(a)(3)(B)(i) and 5(e)(I)(A)(i), based on a finding that the available information is insufficient to permit a reasoned evaluation of the environmental effects of the PMN substance. The order required the Company to submit to EPA certain toxicity testing before any manufacturing, processing, or use of the PMN substance to address potential environmental risks. The Order was also issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present

an unreasonable risk of injury to human health and the environment. Additionally, the Order was issued under TSCA sections 5(a)(3)(B)(ii)(II) and 5(e)(1)(A)(ii)(II), based on a finding that the substance is or will be produced in substantial quantities and that the substance either enters or may reasonably be anticipated to enter the environment in substantial quantities, or there is or may be significant (or substantial) human exposure to the substance.

On January 20, 2020, the Company submitted to EPA the following testing in accordance with the requirements of the Consent Order: an inherent biodegradability study/Zahn-Wellens/EMPA test based on OECD Test Guideline 302B; a freshwater acute fish toxicity study; a marine acute fish toxicity study; an acute aquatic invertebrate toxicity; and an algal toxicity test. The Company also provided a report indicating that the fish acute toxicity mitigated by humic acid test was not conducted as no toxic effects were observed in the fish acute toxicity test. The required ecotoxicity and fate tests were reviewed and found to be acceptable. The results of these tests demonstrated that the substance has low environmental hazard.

On October 18, 2021, EPA issued a modified Consent Order to allow manufacturing, processing, and use of the PMN substance under certain limitations. Based on comparison to analogous chemical substances, EPA has identified concerns for developmental toxicity. Based on the surfactant properties of the PMN substance, EPA has also identified concerns for lung effects. To protect against these human health risks, the consent Order modification requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS;
- No use of the PMN substance in any consumer product to be added to gasoline or diesel fuels by the consumer;
- Use of the PMN substance only for the confidential use allowed in the Order; and
- No manufacture, processing, or use of the PMN substance in any manner that results in inhalation exposure.



The proposed SNUR designates as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has determined that information that would inform the understanding of absorption and developmental effects would be potentially useful to characterize the human health effects of the PMN substance. Although the Order does not require the development of this information, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-18-27 (40 CFR 721.11753).**

*Chemical Name:* 2-Propenoic acid, 2-alkyl-, 2-(dialkylamino)alkyl ester, polymer with alpha-(2-alkyl-1-oxo-2-alken-1-yl)-omega-methoxypoly(oxy-1,2-alkanediyl) (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* December 1, 2021.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substance will be as an additive in coatings. Based on structural alerts for aliphatic amines and polyamines, information provided in the SDS, and comparison to analogous substances, EPA has identified concerns for irritation to the skin, eyes, and respiratory tract, lung effects, and skin sensitization. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified particulate respirator with an APF of at least 50, or of at least 1,000 when spray applied, where there is a potential for inhalation exposure;

- No use of the PMN substance in formulations greater than 0.1% for spray applications;

and

- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity, pulmonary effects, eye irritation, skin irritation, and skin sensitization testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-18-301 (40 CFR 721.11754).**

*Chemical Name:* Alkanedioic acid, polymer with cycloalkyl dimethanol, alkyl and cycloalkyl diisocyanates, dimethyl-alkanediol, dihydroxyalkanoic acid methylenebis[isocyanatocyclohexane, hydroxyethyl acrylate- and polyalkyl glycol monoalkyl ether blocked (generic).

*CAS Number:* Not available.

*Effective date of TSCA Order:* June 22, 2021.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substance will be as a coating component. Based on the TSCA New Chemical Program Chemical Category for acrylates, EPA identified irritation and sensitization hazards for the PMN substance. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may

present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
- No use of the PMN substance in a consumer product.

The proposed SNUR designates as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has determined that information that would inform the understanding of skin irritation and sensitization would be potentially useful to characterize the human health effects of the PMN substance. Although the Order does not require the development of this information, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-18-340 (40 CFR 721.11755).**

*Chemical Name:* Poly(oxy-1,4-butanediyl), alpha-hydro-omega-hydroxy-, polymer with 1,1'-methylenebis[4-isocyanatobenzene], caprolactam-blocked.

*CAS Number:* 2247074-17-3.

*Effective Date of TSCA Order:* March 22, 2022.

*Basis for TSCA Order:* The PMN states that the use of the substance will be for one component thermoset elastomer manufacture. Based on the structural alert for diisocyanates, EPA has identified concerns for skin and respiratory sensitization. Based on test data for the hydrolysis

product caprolactam, EPA has also identified concerns for neurotoxicity, reproductive/developmental toxicity, respiratory tract effects, and systemic effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Establishment of a hazard communication program, including human health

precautionary statements on each label and in the SDS;

- No manufacture without the use of a packed tower scrubber that removes at least 95% of the PMN substance prior to release;

- No manufacturing, processing, or use of the PMN substance in any manner that results in inhalation exposure;

- No use of the PMN substance other than in one component thermoset elastomer manufacture; and

- No use of the PMN substance in a consumer product.

The proposed SNUR designates as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has determined that the results of skin sensitization, reproductive toxicity (developmental effects), pulmonary effects, neurotoxicity, and other specific target organ toxicity testing may be potentially useful to characterize the human health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other

relevant information.

**PMN Number: P-19-165 (40 CFR 721.11756).**

*Chemical Name:* Tall oil pitch, fraction, sterol-low (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* September 24, 2021.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) uses will be as a plasticizer in rubber and an additive for asphalt. EPA is unable to determine acute and chronic concentration of concern values for sediment-dwelling organisms and amphibians due to expected partitioning to sediments and a lack of scientific data to characterize the environmental hazards. The Order was issued under TSCA sections 5(a)(3)(B)(i) and 5(e)(1)(A)(i), based on a finding that the information available to the Agency is insufficient to permit a reasoned evaluation of the health and environmental effects of the new chemical substance. To protect against these risks, the Order requires:

- No release of the PMN substance, or any waste stream containing the PMN substance, into water.

The proposed SNUR would designate as a “significant new use” the absence of this protective measure.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of aquatic toxicity testing may be potentially useful to characterize the environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-20-10 (40 CFR 721.11757).**

*Chemical Name:* Carboxylic acid, reaction products with metal hydroxide, inorganic dioxide and

metal (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* October 15, 2021.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substance will be as a polymerization auxiliary. Based on the potential for chelation of nutrient metals, EPA has identified concerns for developmental and blood effects. Based on test data on components of the PMN substance and test data on a metabolite, EPA has identified concerns for systemic toxicity, reproductive and developmental toxicity, genotoxicity, and skin sensitization. Based on test data on the PMN substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 11 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified particulate respirator with an APF of at least 1,000, or an APF of 50 if dust controls are implemented that demonstrate an exposure reduction of at least 30% where there is a potential for inhalation exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
- No release of the PMN substance resulting in surface water concentrations that exceed 11 ppb.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by

this SNUR. EPA has determined that the results of acute toxicity, skin absorption, skin sensitization, genetic toxicity, specific target organ toxicity, reproductive/developmental toxicity, and neurotoxicity testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Numbers: P-20-62 (40 CFR 721.11758), P-20-63 (40 CFR 721.11759), P-20-64 (40 CFR 721.11760), and P-20-65 (40 CFR 721.11761).**

*Chemical Names:* Multi-walled carbon nanotubes; closed; 4.4 - 12.8 nm diameter; bundle length 10.6 - 211.1 µm; Grade: Jenotube 6 (P-20-62), Multi-walled carbon nanotubes; closed; 5.1 - 11.6 nm diameter; bundle length 1.9 - 552.0 µm; Grade: Jenotube 8 (P-20-63), Multi-walled carbon nanotubes; closed; 7.9 - 14.2 nm diameter; bundle length 9.4 - 106.4 µm; Grade: Jenotube 10 (P-20-64), and Multi-walled carbon nanotubes; closed; 17.0 - 34.7 nm diameter; globular shape; Grade: Jenotube 20 (P-20-65).

*CAS Numbers:* Not available.

*Effective Date of TSCA Order:* October 12, 2021.

*Basis for TSCA Order:* The PMNs state that the use of the substances will be as electrically conductive materials, heat dissipation materials, heat generation materials, additives for weight reduction, additives to improve physical or mechanical properties, additives in batteries, energy storage, and electrode applications, and additives in field emission applications. Based on analogy to asbestos fibers and data for other multi-walled carbon nanotubes, EPA has identified concerns for lung effects (lung overload and lung carcinogenicity) if poorly soluble, respirable particulates and fibers are inhaled. Based on comparison to analogous chemical substances, EPA has identified concerns for eye irritation and systemic effects. Based on the presence of cobalt oxide as a residual at 2.1%, EPA has identified concerns for the P-20-64 chemical substance for acute neurotoxicity, dermal and respiratory sensitization, mutagenicity and carcinogenicity. EPA

was unable to estimate the environmental hazard of these new chemical substances. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- No domestic manufacture (i.e., import only);
- No processing or use of the PMN substances in an application method that generates a vapor, mist, dust, or aerosol unless such application method occurs in an enclosed process;
- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- No manufacture of the PMN substances with a maximum weight % of cobalt oxide impurity in exceedance of 2.1%;
- Process and use of the PMN substances only as electrically conductive materials, heat dissipation materials, heat generation materials, additives for weight reduction, additives to improve physical or mechanical properties, additives in batteries, energy storage, and electrode applications, or as additives in field emission applications;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
- No release of the PMN substances, or any waste stream containing the PMN substances, into water.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by



this SNUR. EPA has determined that the results of specific target organ toxicity, carcinogenicity, eye irritation, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substances. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-20-70 (40 CFR 721.11762).**

*Chemical Name:* Nonanamide, N,N-dimethyl.

*CAS Number:* 6225-08-7.

*Effective Date of TSCA Order:* February 10, 2022.

*Basis for TSCA Order:* The PMN states that the use of the substance will be as a solvent for use in formulated pesticide products. Based on structure and physical/chemical properties, EPA has identified concerns for lung effects (surfactancy) and aspiration. Based on submitted test data and comparison to analogous chemical substances, EPA has also identified concerns for irritation to the skin and eyes, systemic effects, and reproductive/developmental effects. Based on comparison to an analogous chemical substance, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 96 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified gas/vapor respirator with an APF of at least 10 where there is a potential for inhalation exposure;
- No processing use of the PMN substance other than as a solvent for use in formulated pesticide products;
- No manufacture of the PMN substance other than by import into the United States (i.e., no domestic manufacture) using 20,000 kg International Organization for Standardization tank

containers (ISOtainers) or 1,000 kg intermediate bulk containers (IBCs);

- No release of the PMN substance resulting in surface water concentrations that exceed 96 ppb; and

- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of chronic aquatic toxicity testing may be potentially useful to characterize the environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-20-84 (40 CFR 721.11763).**

*Chemical Name:* 2-Propenoic acid, 2-methyl, 2-(dimethylamino)ethyl ester, polymers with 2-(C16-18-acylamino)ethyl acrylate and hydroxyalkyl acrylate, acetates (salts) (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* October 20, 2021.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substance will be as a paper treatment additive. Based on the pH of the PMN substance, EPA has identified concerns for skin, eye, and respiratory tract irritation. Based on analogue data, EPA has also identified concerns for lung effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- No processing or use of the PMN substance in any manner that results in inhalation exposure;
- No use of the PMN substance in a product applied by a consumer; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of specific target organ toxicity and pulmonary effects testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-20-105 (40 CFR 721.11764).**

*Chemical Name:* 4H-Pyran-4-one, 3-[(2,5-dihydro-4-methyl-5-oxo-2-furanyl)oxy]-2-methyl.

*CAS Number:* 1333341-34-6.

*Effective Date of TSCA Order:* November 9, 2021.

*Basis for TSCA Order:* The PMN states that the use of the substance will be to promote microbial activity in the soil, resulting in increased availability of nutrients in the soil, including nitrogen and phosphorus, for crops (for use on commercial farming operations). Based on test data on the PMN substance, EPA has identified concerns for skin and eye irritation. Based on comparison to analogous substances, EPA has also identified concerns systemic effects and reproductive/developmental effects. Based on comparison to analogous vinyl esters, EPA predicts that toxicity to aquatic organisms may occur at concentrations that exceed 5 ppb. The

Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified particulate respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- No processing of the PMN substance other than in a facility that employs an on-site sump system used to capture fugitive dust releases and disposes the solid waste captured by this sump system by landfill;
- No processing of the PMN substance except under negative pressure when transferring the substance as a solid material in order to minimize exposures to fugitive dust/particulates;
- No domestic manufacture of the PMN substance (i.e., import only);
- No use of the PMN substance in a consumer product;
- No use of the PMN substance in spray applications at a concentration exceeding 0.01% in formulation;
- No use of the PMN substance other than to promote microbial activity in the soil, resulting in increased availability of nutrients in the soil, including nitrogen and phosphorus, for crops (for use on commercial farming operations); and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by

this SNUR. EPA has determined that the results of specific target organ toxicity and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-20-127 (40 CFR 721.11765).**

*Chemical Name:* 2H-Pyran, tetrahydro-4-methyl.

*CAS Number:* 4717-96-8.

*Effective Date of TSCA Order:* December 21, 2021.

*Basis for TSCA Order:* The PMN states that the use of the substance will be as an industrial solvent. Based on submitted test data, EPA has identified concerns for aspiration, skin corrosion, serious eye damage, systemic effects including central nervous system effects, and reproductive and developmental toxicity. Based on comparison to analogous neutral organic substances, EPA has determined that toxicity to aquatic organisms may occur at concentrations that exceed 540 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of a NIOSH-certified particulate respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- No use of the PMN substance in a consumer product;
- Use of personal protective equipment where there is a potential for dermal exposure;
- No release of the PMN substance resulting in surface water concentrations that exceed 540 ppb; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of aquatic toxicity testing may be potentially useful to characterize the environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-20-130 (40 CFR 721.11766).**

*Chemical Name:* Organic acid ester, polymer with aliphatic diols and 1,1'-methylenebis[4-isocyanatobenzene] (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* March 22, 2022.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substance will be as a component of industrial coatings. Based on a structural alert for isocyanates and information provided in the SDS, EPA has identified concerns for dermal and respiratory sensitization and lung damage. Based on test data for methylene diphenyl diisocyanate (MDI) and other confidential analogous chemical substances, EPA has also identified concerns for portal-of-entry inhalation effects, lung effects, lymph node effects, carcinogenicity, genotoxicity, skin and eye irritation, and dermal and respiratory sensitization. Based on test data for 4,4'-Methylenedianiline (MDA), the hydrolysis product of MDI, EPA has identified concerns for acute toxicity, clinical signs, genotoxicity, carcinogenicity, eye irritation, skin irritation, skin sensitization, and body weight, blood, stomach, liver, kidney, thyroid, spleen, reproductive, and eye effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation,

the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified Gas/Vapor respirator with an APF of at least 50 where there is a potential for inhalation exposure;
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS;
- No use of the PMN substance in any manner or method that involves spray application;
- No use of the PMN substance in a consumer product; and
- No release of the PMN substance to water.

The proposed SNUR designates as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that would be designated by this SNUR. EPA has determined that worker exposure data may be potentially useful to characterize human health effects of the PMN substance. Although the Order does not require this, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-21-3 (40 CFR 721.11767).**

*Chemical Name:* 4,4-Methylenebis (2,6-dimethyl phenol) polymer with 2-(chloromethyl)oxirane, 1,4-benzene diol, 2-methyl-2-propenoic acid, mixed alkyl substituted 2-methyl 2-propenoate, and ethyl 2-propenoate, reaction products with 2-(dimethylamino) ethanol (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* March 10, 2022.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substance

will be as a polymeric film former for coatings. Based on structural alerts for amines and acid groups, EPA has identified concerns for irritation to the skin, eyes, and respiratory tract. Based on a potential metabolite released from the anion, EPA has identified concerns for developmental effects. Based on potential for chelation of nutrient metals by the acid groups of the anion, EPA has also identified developmental, blood, liver, and kidney effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified Gas/Vapor respirator with an APF of at least 10 where there is a potential for inhalation exposure;
- No use of the PMN substance in a consumer product; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of developmental toxicity, skin irritation, and eye damage testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Numbers: P-21-28 (40 CFR 721.11768) and P-21-29 (40 CFR 721.11769).**



*Chemical Names:* Phenol, methylethylidene, polymer chloromethyl epoxide and methylethylidene bis-oxy, bis-amine (generic) (P-21-28) and Amine, methylethylidene bis(oxy) (generic) (P-21-29).

*CAS Numbers:* Not available.

*Effective Date of TSCA Order:* November 9, 2021.

*Basis for TSCA Order:* The PMNs state that the use of the substances will be as an epoxy polymer used in reaction to make epoxy (P-21-28) and an epoxy monomer used in polymer reactions (P-21-29). Based on test data on the residual and an analogue, EPA has identified concerns for corrosion to the skin, eyes, and respiratory tract, acute toxicity, systemic effects, irritation to the skin and eyes, and skin sensitization. Based on analogy to diamines, EPA has identified concerns for respiratory sensitization. Based on comparison to analogous aliphatic amines, EPA predicts that toxicity to aquatic organisms may occur at concentrations that exceed 100 ppb (for P-21-28) and 840 ppb (for P-21-29). The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substances may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified particulate respirator with an APF of at least 50 for non-spray applications or 1,000 for spray applications where there is a potential for inhalation exposure (P-21-28);
- Use of a NIOSH-certified gas/vapor respirator with an APF of at least 50 (non-spray applications) or a NIOSH-certified combination particulate and gas/vapor respirator with an APF of at least 1,000 (spray applications) where there is a potential for inhalation exposure (P-21-29);
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
- No release of the PMN substances resulting in surface water concentrations that exceed

100 ppb for P-21-28 or 840 ppb for P-21-29.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of metabolism or pharmacokinetics, specific target organ toxicity, skin irritation/corrosion, skin irritation/eye damage, skin sensitization, aquatic toxicity (P-21-28), and chronic aquatic toxicity (P-21-29) testing may be potentially useful to characterize the human health and environmental effects of the PMN substances.

Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-21-34 (40 CFR 721.11770).**

*Chemical Name:* Carbamic acid, N-[3-(trialkoxysilyl)propyl]-, C,C'-[2,2,4(or 2,4,4)-trimethyl-1,6-hexanediyl] ester (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* February 27, 2022.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substances will be as a crosslinker for automotive coatings and a crosslinker for wood and plastic coatings. Based on comparison to analogous substances, EPA has identified concerns for respiratory tract effects and systemic, reproductive, and developmental effects. Based on comparison to analogous alkoxysilanes, EPA has determined that toxicity to aquatic organisms may occur at concentrations that exceed 1 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- No release of the PMN substance resulting in surface water concentrations that exceed 1 ppb; and

- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of metabolism or pharmacokinetics, specific target organ toxicity, reproductive toxicity, developmental toxicity, and biodegradation testing may be potentially useful to characterize the health and fate effects of the PMN substance.

Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-21-67 (40 CFR 721.11771).**

*Chemical Name:* Arylfurandione, [bis(trihaloalkyl)alkylidene]bis-, polymer with alkanediamine (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* December 8, 2021.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substance will be as a polymer used in the manufacture of films. Based on the high molecular weight and low water solubility of the PMN substance, EPA has identified concerns for lung effects. Based on structural alerts and information provided in the SDS, EPA has also identified concerns for dermal irritation. For the incineration product, EPA has identified concerns for systemic effects. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the

substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Manufacture or processing of the PMN substance only at a particle size of 10 microns or greater;
- Use of personal protective equipment where there is a potential for dermal exposure;
- Whenever the PMN substance or waste streams containing the PMN substance are disposed of by incineration, such incineration must occur at a minimum temperature of 870 degrees Celsius; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation testing may be potentially useful to characterize the health effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-21-93 (40 CFR 721.11772).**

*Chemical Name:* Phosphonic acid, dimethyl ester, reaction products with alkyl-alkyl-alkanediol and alkanediol (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* December 1, 2021.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substance will be as an anti-wear additive for lubricants. Based on a test data on the PMN substance, EPA

has identified concerns for skin corrosion, developmental toxicity, neurotoxicity, and systemic effects. Based on information provided in the SDS, EPA has also identified concerns for skin corrosion, serious eye damage, respiratory tract irritation, and developmental toxicity. Based on residual feedstock and the potential for methanol release, EPA has also identified concerns for eye irritation, systemic toxicity, neurotoxicity, and developmental effects. Based on comparison to analogous esters, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 180 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- No manufacture, processing, or use of the PMN substance in any manner that generates a dust, mist, particulate, or aerosol that results in inhalation exposure;
- No use of the PMN substance in consumer products where the concentration of the PMN substance equals or exceeds 3%;
- No release of the PMN substance resulting in surface water concentrations that exceed 180 ppb; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of aquatic toxicity and fate testing may be potentially useful to characterize the environmental effects of the PMN substance. Although the

Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-21-94 (40 CFR 721.11773).**

*Chemical Name:* Silane, halogenated (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* January 20, 2022.

*Basis for TSCA Order:* The PMN states that the use of the substance will be as a deposition precursor for the manufacture of electronic components. Based on the reactivity of the PMN substance, information in the SDS, and analogue data for dichlorosilane and silicon tetrachloride, EPA has identified concerns for corrosion to skin, eyes, and the respiratory tract. Based on analogue test data for dichlorosilane, EPA has also identified concerns for systemic effects. Based on test data on a disassociation product, EPA has also identified concerns for thyroid effects, immunotoxicity, and developmental neurotoxicity. Based on comparison to an analogous chemical substance, EPA predicts that toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified respirator with an APF of at least 1,000 where there is a potential for inhalation exposure, or compliance with an NCEL of 0.05 mg/m<sup>3</sup> as an 8-hour time-weighted average to prevent inhalation exposure;
- No use of the PMN substance other than as a deposition precursor in the manufacture of electronic components;
- No release of the PMN substance resulting in surface water concentrations that exceed 3 ppb; and

- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin corrosion, eye damage, specific target organ toxicity, pulmonary effects, developmental neurotoxicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-21-115 (40 CFR 721.11774).**

*Chemical Name:* Heteromonocycle, polymer, substituted aliphatic carbamate, [2-[(1-oxo-2-propen-1-yl)oxy]alkyl]ester (generic).

*CAS Number:* Not available.

*Effective Date of TSCA Order:* November 3, 2021.

*Basis for TSCA Order:* The PMN states that the generic (non-confidential) use of the substance will be as a raw material for industrial additive manufacturing, UV-curable inks, coatings, and adhesives. Based on the presence of bifunctional acrylates and information provided in the TSCA New Chemical Program Chemical Categories for acrylates, EPA has identified concerns for irritation to the skin, eyes, and respiratory tract, and skin and respiratory sensitization. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- Use of a NIOSH-certified particulate respirator with an APF of at least 50, or of at least 1,000 when spray applied, where there is a potential for inhalation exposure;
- No use of the PMN substance in a consumer product; and
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation, sensitization, and eye damage testing may be potentially useful to characterize the health effects of the PMN substance.

Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-21-141 (40 CFR 721.11775).**

*Chemical Name:* Alkanes, C4-8-branched and linear.

*CAS Number:* 2529890-37-5.

*Effective Date of TSCA Order:* January 4, 2022.

*Basis for TSCA Order:* The PMN states that the use of the substance will be as a transportation fuel. Based on the constituents of the PMN substance, EPA has identified concerns for skin and eye irritation, respiratory depression/irritation, acute toxicity, neurotoxicity, systemic toxicity, neurotoxicity, body weight effects, reproductive and developmental toxicity, and genotoxicity. Based on an analogue mixture, EPA has also identified concerns for respiratory tract effects and carcinogenicity. Based on the chemical composition as a petroleum replacement, EPA has also identified concerns for hydrocarbon pneumonia/aspiration. Based on comparison to analogous



neutral organic substances, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 3 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Use of personal protective equipment where there is a potential for dermal exposure;
- and
- No manufacturing, processing, or use of the PMN substance other than for use as a transportation fuel, refinery feedstock; or fuel blending additive.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of skin irritation, eye irritation, respiratory depression/irritation, hydrocarbon pneumonia/aspiration, reproductive and developmental toxicity, systemic toxicity, genotoxicity, carcinogenicity, and aquatic toxicity testing may be potentially useful to characterize the health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order’s restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

**PMN Number: P-21-196 (40 CFR 721.11776).**

*Chemical Name:* 5H-1,2-Oxathiole, 2,2-dioxide.

*CAS Number:* 21806-61-1.

*Effective Date of TSCA Order:* June 20, 2022.

*Basis for TSCA Order:* The PMN states that the use of the substance will be as an additive in battery electrolyte formulations. Based on information provided in the SDS, EPA has identified

concerns for acute toxicity, eye irritation, genotoxicity, and carcinogenicity. Based on OECD Toolbox results, EPA has identified concerns for skin sensitization. Based on submitted test data, EPA has identified concerns for acute toxicity, skin sensitization, genotoxicity, neurotoxicity, reproductive, and developmental effects. Based on alkylating potential of the PMN substance, EPA has identified concerns for eye irritation, skin sensitization, acute toxicity, genotoxicity, carcinogenicity, and liver and developmental effects. Based on test data for analogous substance, EPA has also identified concerns for acute toxicity, clinical signs, eye irritation and corrosion, genotoxicity, and carcinogenicity. Based on submitted test data, EPA predicts toxicity to aquatic organisms may occur at concentrations that exceed 23 ppb. The Order was issued under TSCA sections 5(a)(3)(B)(ii)(I) and 5(e)(1)(A)(ii)(I), based on a finding that in the absence of sufficient information to permit a reasoned evaluation, the substance may present an unreasonable risk of injury to human health or the environment. To protect against these risks, the Order requires:

- Manufacture of the PMN substance only by import into the United States (i.e., no domestic manufacture).
- Process and use of the PMN substance only in an enclosed process except that sampling and equipment cleaning operations need not occur in an enclosed process. During sampling and equipment cleaning operations each person is required to wear a National Institute for Occupational Safety and Health (NIOSH)-certified full-face respirator with an Assigned Protection Factor (APF) of 1,000 and dermal personal protective equipment.
- Establishment of a hazard communication program, including human health precautionary statements on each label and in the SDS; and
- Disposal of the PMN substance only by incineration with 99.9% efficiency.

The proposed SNUR would designate as a “significant new use” the absence of these protective measures.

*Potentially Useful Information:* EPA has determined that certain information may be potentially useful in support of a request by the PMN submitter to modify the Order, or if a manufacturer or

processor is considering submitting a SNUN for a significant new use that will be designated by this SNUR. EPA has determined that the results of neurotoxicity, carcinogenicity, and aquatic toxicity testing may be potentially useful to characterize the human health and environmental effects of the PMN substance. Although the Order does not require these tests, the Order's restrictions remain in effect until the Order is modified or revoked by EPA based on submission of this or other relevant information.

## **VI. Applicability of the Proposed Significant New Use Designation**

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this proposed rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted EPA concludes that the designated significant new uses are not ongoing.

When chemical substances identified in this proposed rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, TSCA Orders have been issued for these chemical substances, and the PMN submitters are prohibited by the TSCA Orders from undertaking activities which would be designated as significant new uses. The identities of many of the chemical substances subject to this proposed rule have been claimed as confidential per 40 CFR 720.85. Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this proposed rule are ongoing.

EPA designates [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

In the unlikely event that a person began commercial manufacture or processing of the

chemical substances for a significant new use identified as of that date would have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and wait until EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken such actions as are required with that determination.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Chemical Substance Inventory (TSCA Inventory). Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <https://www.epa.gov/tsca-inventory>.

## **VII. Development and Submission of Information**

EPA recognizes that TSCA section 5 does not require developing any particular new information (e.g., generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, TSCA Order or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, Order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or control and to describe any other information known or reasonably ascertainable (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit V. lists potentially useful information for the SNURs listed in this document. Descriptions of this information is provided for informational purposes. The potentially useful information identified in Unit V. will be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use.

EPA strongly encourages persons, before performing any testing, to consult with the Agency. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages dialog with the Agency on the use of alternative test

methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, visit <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>.

In some of the TSCA Orders for the chemical substances identified in this rule, EPA has established time limits in view of the lack of data on the potential health and environmental risks that may be posed by the significant new uses or increased exposure to the chemical substances. These limits cannot be exceeded unless the PMN submitter first submits the results of specified tests that would permit a reasoned evaluation of the potential risks posed by these chemical substances. The SNURs contain the same time limits as the TSCA Orders. Exceeding these production limits is defined as a significant new use. Persons who intend to exceed the time limit must notify the Agency by submitting a SNUN at least 90 days in advance of commencement of non-exempt commercial manufacture or processing.

Any request by EPA for the triggered and pended testing described in the TSCA Orders was made based on EPA's consideration of available screening-level data, if any, as well as other available information on appropriate testing for the PMN substances. Further, any such testing request on the part of EPA that includes testing on vertebrates was made after consideration of available toxicity information, computational toxicology and bioinformatics, and high-throughput screening methods and their prediction models.

The potentially useful information listed in Unit V. may not be the only means of addressing the potential risks of the chemical substance. However, submitting a SNUN without any test data or other information may increase the likelihood that EPA will take action under TSCA section 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

## **VIII. SNUN Submissions**

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40. E-PMN software is available electronically at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

## **IX. Economic Analysis**

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this proposed rule. EPA's complete economic analysis is available in the docket for this rulemaking.

## **X. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive orders can be found at <https://www.epa.gov/laws-regulations-and-executive-orders>.

*A. Executive Orders 12866: Regulatory Planning and Review and 13563: Improving Regulations and Regulatory Review*

This action proposes to establish SNURs for several new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and

13563 (76 FR 3821, January 21, 2011).

*B. Paperwork Reduction Act (PRA)*

According to the PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the *Federal Register*, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection activities associated with SNURs have already been approved by OMB under the PRA and assigned OMB control number 2070-0012 (EPA ICR No. 574). This proposed rule does not contain any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including using automated collection techniques, to the Director, Regulatory Support Division, Office of Mission Support (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

*C. Regulatory Flexibility Act (RFA)*

Pursuant to the RFA section 605(b) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that promulgation of these SNURs would not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including small or large entities) who intends to engage in any activity described in the final rule

as a “significant new use.” Because these uses are “new,” based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 10 in FY2016, 14 in FY2017, and 18 in FY2018 and only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$19,020 to \$3,330. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$11,164 for qualifying small firms. Therefore, the potential economic impacts of complying with this proposed SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the *Federal Register* of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

#### *D. Unfunded Mandates Reform Act (UMRA)*

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this proposed rule would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

#### *E. Executive Order 13132: Federalism*

This action would not have a substantial direct effect on States, on the relationship



between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

*F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action would not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it is not expected to have substantial direct effects on Indian Tribes. This action would not significantly nor uniquely affect the communities of Indian Tribal governments, nor would it involve or impose any requirements that affect Indian Tribes.

*G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action has not otherwise been designated as a significant energy action by the Administrator of OMB's Office of Information and Regulatory Affairs.

*I. National Technology Transfer and Advancement Act (NTTAA)*

This action does not involve any technical standards subject to NTTAA section 12(d) (15 U.S.C. 272 note).

*J. Executive Orders 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations and 14008: Tackling the Climate Crisis at Home and Abroad*

EPA believes that this action is not subject to Executive Orders 12898 (59 FR 7629, February 16, 1994) and 14008 (86 FR 7619, January 27, 2021) because it does not establish an environmental health or safety standard.

**List of Subjects**

*40 CFR Part 721*

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: October 20, 2022.

**Tala Henry,**

*Deputy Director, Office of Pollution Prevention and Toxics.*

Therefore, for the reasons stated in the preamble, it is proposed that 40 CFR chapter I be amended as follows:

## **PART 721 - SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES**

1. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

2. Add §§ 721.11752 through 721.11776 to subpart E to read as follows:

### **Subpart E—Significant New Uses for Specific Chemical Substances**

Sec.

\* \* \* \* \*

721.11752 Quaternary ammonium salt of polyisobutene succinic acid (generic).

721.11753 2-Propenoic acid, 2-alkyl-, 2-(dialkylamino)alkyl ester, polymer with alpha-(2-alkyl-1-oxo-2-alken-1-yl)-omega-methoxypoly(oxy-1,2-alkanediyl) (generic).

721.11754 Alkanedioic acid, polymer with cycloalkyl dimethanol, alkyl and cycloalkyl diisocyanates, dimethyl-alkanediol, dihydroxyalkanoic acid methylenebis[isocyanatocyclohexane, hydroxyethyl acrylate- and polyalkyl glycol monoalkyl ether blocked (generic)

721.11755 Poly(oxy-1,4-butanediyl), alpha-hydro-omega-hydroxy-, polymer with 1,1'-methylenebis[4-isocyanatobenzene], caprolactam-blocked.

721.11756 Tall oil pitch, fraction, sterol-low (generic).

721.11757 Carboxylic acid, reaction products with metal hydroxide, inorganic dioxide and metal (generic).

721.11758 Multi-walled carbon nanotubes; closed; 4.4 - 12.8 nm diameter; bundle length 10.6 - 211.1 µm; Grade: Jenotube 6.

721.11759 Multi-walled carbon nanotubes; closed; 5.1 - 11.6 nm diameter; bundle length 1.9 - 552.0 µm; Grade: Jenotube 8.

721.11760 Multi-walled carbon nanotubes; closed; 7.9 - 14.2 nm diameter; bundle length 9.4 - 106.4 µm; Grade: Jenotube 10.

721.11761 Multi-walled carbon nanotubes; closed; 17.0 - 34.7 nm diameter; globular shape; Grade: Jenotube 20.

721.11762 Nonanamide, N,N-dimethyl.

721.11763 2-Propenoic acid, 2-methyl, 2-(dimethylamino)ethyl ester, polymers with 2-(C16-18-acylamino)ethyl acrylate and hydroxyalkyl acrylate, acetates (salts) (generic).

721.11764 4H-Pyran-4-one, 3-[(2,5-dihydro-4-methyl-5-oxo-2-furanyl)oxy]-2-methyl.

721.11765 2H-Pyran, tetrahydro-4-methyl.

721.11766 Organic acid ester, polymer with aliphatic diols and 1,1'-methylenebis[4-isocyanatobenzene] (generic).

721.11767 4,4-Methylenebis (2,6-dimethyl phenol) polymer with 2-(chloromethyl)oxirane, 1,4-benzene diol, 2-methyl-2-propenoic acid, mixed alkyl substituted 2-methyl 2-propenoate, and ethyl 2-propenoate, reaction products with 2-(dimethylamino) ethanol (generic). 21-3

721.11768 Phenol, methylethylidene, polymer chloromethyl epoxide and methylethylidene bis-oxy, bis-amine (generic).

721.11769 Amine, methylethylidene bis(oxy) (generic)

721.11770 Carbamic acid, N-[3-(trialkoxysilyl)propyl]-, C,C'-[2,2,4(or 2,4,4)-trimethyl-1,6-

hexanediyl] ester (generic).

721.11771 Arylfurandione, [bis(trihaloalkyl)alkylidene]bis-, polymer with alkanediamine (generic).

721.11772 Phosphonic acid, dimethyl ester, reaction products with alkyl-alkyl-alkanediol and alkanediol (generic).

721.11773 Silane, halogenated (generic).

721.11774 Heteromonocycle, polymer, substituted aliphatic carbamate, [2-[(1-oxo-2-propen-1-yl)oxy]alkyl]ester (generic).

721.11775 Alkanes, C4-8-branched and linear.

721.11776 5H-1,2-Oxathiole, 2,2-dioxide.

\* \* \* \* \*

#### **§ 721.11752 Quaternary ammonium salt of polyisobutene succinic acid (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as quaternary ammonium salt of polyisobutene succinic acid (PMN P-16-349) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (6)(vii), (7), and (c). For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1)(ix), (2)(i) and (v), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(k). It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure. It is a significant new use to use the substance in any consumer product to be added to gasoline or diesel fuels by the consumer.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11753 2-Propenoic acid, 2-alkyl-, 2-(dialkylamino)alkyl ester, polymer with alpha-(2-alkyl-1-oxo-2-alken-1-yl)-omega-methoxypoly(oxy-1,2-alkanediyl) (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 2-propenoic acid, 2-alkyl-, 2-(dialkylamino)alkyl ester, polymer with alpha-(2-alkyl-1-oxo-2-alken-1-yl)-omega-methoxypoly(oxy-1,2-alkanediyl) (PMN P-18-27) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured) or when present as an impurity at less than 1% by weight.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5) through (8), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50 or of at least 1,000 during spray applications.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), and (5). For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity; skin irritation; eye irritation; skin sensitization. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance in formulations at greater than 0.1% for spray applications.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i)

are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11754 Alkanedioic acid, polymer with cycloalkyl dimethanol, alkyl and cycloalkyl diisocyanates, dimethyl-alkanediol, dihydroxyalkanoic acid methylenebis [isocyanatocyclohexane, hydroxyethyl acrylate- and polyalkyl glycol monoalkyl ether blocked (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkanedioic acid, polymer with cycloalkyl dimethanol, alkyl and cycloalkyl diisocyanates, dimethyl-alkanediol, dihydroxyalkanoic acid methylenebis [isocyanatocyclohexane, hydroxyethyl acrylate- and polyalkyl glycol monoalkyl ether blocked (PMN P-18-301) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (7), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; skin sensitization; eye irritation; respiratory sensitization. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11755 Poly(oxy-1,4-butanediyl), alpha-hydro-omega-hydroxy-, polymer with 1,1'-methylenebis[4-isocyanatobenzene),caprolactam-blocked.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as poly(oxy-1,4-butanediyl), alpha-hydro-omega-hydroxy-, polymer with 1,1'-methylenebis[4-isocyanatobenzene),caprolactam-blocked (P-18-340; CAS No. 2247074-17-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3) and (7), and (c).

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), and (5). For purposes of § 721.72(g)(1), this substance may cause: respiratory sensitization; skin sensitization; reproductive toxicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to use the substance other than for one component thermoset elastomer manufacture. It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure. It is a significant new use to manufacture the substance without the use of a packed tower scrubber that removes at least 95 percent of the substance prior to release.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11756 Tall oil pitch, fraction, sterol-low (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as tall oil pitch, fraction, sterol-low (PMN P-19-165) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11757 Carboxylic acid, reaction products with metal hydroxide, inorganic dioxide and metal (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as carboxylic acid, reaction products with metal hydroxide, inorganic dioxide and metal (PMN P-20-10) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).



(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(vii), (7), (8), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000, or an APF of 50 if dust controls are implemented that demonstrate an exposure reduction of at least 30%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization; genetic toxicity; reproductive toxicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=11.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11758 Multi-walled carbon nanotubes; closed; 4.4 - 12.8 nm diameter; bundle length 10.6 - 211.1 µm; Grade: Jenotube 6.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as multi-walled carbon nanotubes; closed; 4.4 - 12.8 nm diameter; bundle length 10.6 - 211.1 µm; Grade: Jenotube 6 (PMN P-20-62) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been

completely reacted or cured or incorporated into an article.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(vii), (7), (8), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization; eye irritation; respiratory sensitization; carcinogenicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to manufacture the substance with a maximum weight percent of cobalt oxide impurity in excess of 2.1%. It is a significant new use to process or use the substance other than as an electrically conductive material, a heat dissipation material, a heat generation material, an additive for weight reduction, an additive to improve physical or mechanical properties, an additive in batteries, energy storage, and electrode applications, or an additive in field emission applications. It is a significant new use to process or use the substance in application methods that do not generate a vapor, mist, dust, or aerosol unless such an application method occurs in an enclosed process.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11759 Multi-walled carbon nanotubes; closed; 5.1 - 11.6 nm diameter; bundle length 1.9 - 552.0 µm; Grade: Jenotube 8.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as multi-walled carbon nanotubes; closed; 5.1 - 11.6 nm diameter; bundle length 1.9 - 552.0 µm; Grade: Jenotube 8 (PMN P-20-63) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured or incorporated into an article.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(vii), (7), (8), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization; eye irritation; respiratory sensitization; carcinogenicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to manufacture the substance with a maximum weight percentage of cobalt oxide impurity in excess of 2.1%. It is a significant new use to process or use the substance other than as an electrically conductive material, a heat dissipation material, a heat generation material, an additive for weight reduction, an additive to improve physical or mechanical properties, an additive in batteries, energy storage, and electrode applications, or an additive in field emission applications. It is a significant new use to process or use the substance in application methods that do not generate a vapor, mist, dust, or aerosol unless such an application method occurs in an enclosed process.

(iv) *Release to water*. Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

**§ 721.11760 Multi-walled carbon nanotubes; closed; 7.9 - 14.2 nm diameter; bundle length 9.4 - 106.4 µm; Grade: Jenotube 10.**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified as multi-walled carbon nanotubes; closed; 7.9 - 14.2 nm diameter; bundle length 9.4 - 106.4 µm; Grade: Jenotube 10 (PMN P-20-64) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured or incorporated into an article.

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(3), (5), (6)(vii), (7), (8), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization; eye irritation; respiratory sensitization; carcinogenicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities*. Requirements as specified in § 721.80(f). It is a significant new use to manufacture the substance with a maximum weight

percentage of cobalt oxide impurity in excess of 2.1%. It is a significant new use to process or use the substance other than as an electrically conductive material, a heat dissipation material, a heat generation material, an additive for weight reduction, an additive to improve physical or mechanical properties, an additive in batteries, energy storage, and electrode applications, or an additive in field emission applications. It is a significant new use to process or use the substance in application methods that do not generate a vapor, mist, dust, or aerosol unless such an application method occurs in an enclosed process.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11761 Multi-walled carbon nanotubes; closed; 17.0 - 34.7 nm diameter; globular shape; Grade: Jenotube 20.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as multi-walled carbon nanotubes; closed; 17.0 - 34.7 nm diameter; globular shape; Grade: Jenotube 20 (PMN P-20-65) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted or cured or incorporated into an article.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(vii), (7), (8), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin sensitization; eye irritation; respiratory sensitization; carcinogenicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to manufacture the substance with a maximum weight percentage of cobalt oxide impurity in excess of 2.1%. It is a significant new use to process or use the substance other than as an electrically conductive material, a heat dissipation material, a heat generation material, an additive for weight reduction, an additive to improve physical or mechanical properties, an additive in batteries, energy storage, and electrode applications, or an additive in field emission applications. It is a significant new use to process or use the substance in application methods that do not generate a vapor, mist, dust, or aerosol unless such an application method occurs in an enclosed process.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

#### **§ 721.11762 Nonanamide, N,N-dimethyl.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as nonanamide, N,N-dimethyl (PMN P-20-70; CAS No. 6225-08-7) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(v), (vi), (7), (8), (b), and (c). For purposes of § 721.63(b), the concentration is set at 1.0%. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; specific target organ toxicity; reproductive toxicity; aspiration hazard. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a solvent for use in formulated pesticide products. It is a significant new use to manufacture the substance other than by import into the United States (i.e., no domestic manufacture) using 20,000 kg International Organization for Standardization tank containers (ISOtainers) or 1,000 kg intermediate bulk containers (IBCs).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=96.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11763 2-Propenoic acid, 2-methyl, 2-(dimethylamino)ethyl ester, polymers with 2-(C16-18-acylamino)ethyl acrylate and hydroxyalkyl acrylate, acetates (salts) (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 2-propenoic acid, 2-methyl, 2-(dimethylamino)ethyl ester, polymers with 2-(C16-18-acylamino)ethyl acrylate and hydroxyalkyl acrylate, acetates (salts) (PMN P-20-84) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3) and (7), (b), and (c). For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o). It is a significant new use to process or use the substance in any manner that results in inhalation exposure.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11764 4H-Pyran-4-one, 3-[(2,5-dihydro-4-methyl-5-oxo-2-furanyl)oxy]-2-methyl.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 4H-pyran-4-one, 3-[(2,5-dihydro-4-methyl-5-oxo-2-furanyl)oxy]-2-



methyl (PMN P-20-105; CAS No. 1333341-34-6) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(vii), (7), (8), (b), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity; reproductive toxicity; skin irritation; eye irritation. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (o). It is a significant new use to process the substance other than in a facility that employs an on-site sump system used to capture fugitive dust releases and disposes the solid waste captured by this sump system by landfill. It is a significant new use to process the substance except under negative pressure when transferring the substance as a solid material in order to minimize exposures to fugitive dust/particles. It is a significant new use to use the substance in spray applications at a concentration exceeding 0.01% in formulation. It is a significant new use to use the substance other than to promote microbial activity in the soil, resulting in increases availability of nutrients in the soil, including nitrogen and phosphorus, for crops (for use on commercial farming operations).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11765 2H-Pyran, tetrahydro-4-methyl.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2H-pyran, tetrahydro-4-methyl (PMN P-20-127; CAS No. 4717-96-8) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(v), (vi), (7), (8), (b), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin corrosion; serious eye damage; specific target organ toxicity; aspiration hazard. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=540.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of §

721.185 apply to this section.

**§ 721.11766 Organic acid ester, polymer with aliphatic diols and 1,1'-methylenebis[4-isocyanatobenzene] (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as organic acid ester, polymer with aliphatic diols and 1,1'-methylenebis[4-isocyanatobenzene] (PMN P-20-130) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(ix), (7), (8), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin irritation; respiratory sensitization; skin sensitization; genetic toxicity; carcinogenicity; reproductive toxicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer use.* Requirements as specified in § 721.80(o). It is a significant new use to use the substance in any manner or method that involves spray application.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(1), (b)(1), and (c)(1).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i),

and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11767 4,4-Methylenebis (2,6-dimethyl phenol) polymer with 2-(chloromethyl)oxirane, 1,4-benzene diol, 2-methyl-2-propenoic acid, mixed alkyl substituted 2-methyl 2-propenoate, and ethyl 2-propenoate, reaction products with 2-(dimethylamino) ethanol (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 4,4-methylenebis (2,6-dimethyl phenol) polymer with 2-(chloromethyl)oxirane, 1,4-benzene diol, 2-methyl-2-propenoic acid, mixed alkyl substituted 2-methyl 2-propenoate, and ethyl 2-propenoate, reaction products with 2-(dimethylamino) ethanol (PMN P-21-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(vii), (7), (8), (b), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 10. For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation. For purposes of § 721.72(e), the concentration is set at 1.0%. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11768 Phenol, methylethylidene, polymer chloromethyl epoxide and methylethylidene bis-oxy, bis-amine (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phenol, methylethylidene, polymer chloromethyl epoxide and methylethylidene bis-oxy, bis-amine (PMN P-21-28) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(vii), (7), (8), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50 in non-spray applications and 1,000 in spray applications.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f) (g)(1), (3)(iii), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin corrosion; skin irritation; serious eye damage; eye irritation; respiratory sensitization; skin sensitization; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=100.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11769 Amine, methylethylidene bis(oxy) (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as amine, methylethylidene bis(oxy) (generic) (PMN P-21-29) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(vii), (7), (8), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50 in non-spray applications and 1,000 in spray applications.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f) (g)(1), (3)(iii), and (5). For purposes of § 721.72(g)(1), this substance may cause: acute toxicity; skin corrosion; skin irritation; serious eye damage; eye irritation; respiratory sensitization; skin sensitization; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=840.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section

except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (h), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

**§ 721.11770 Carbamic acid, N-[3-(trialkoxysilyl)propyl]-, C,C'-[2,2,4(or 2,4,4)-trimethyl-1,6-hexanediyl] ester (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as carbamic acid, N-[3-(trialkoxysilyl)propyl]-, C,C'-[2,2,4(or 2,4,4)-trimethyl-1,6-hexanediyl] ester (PMN P-21-34) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(ii) *Release to water*. Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=1.

(b) *Specific requirements*. The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (c), (f), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements*. The provisions of §

721.185 apply to this section.

**§ 721.11771 Arylfurandione, [bis(trihaloalkyl)alkylidene]bis-, polymer with alkanediamine (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as arylfurandione, [bis(trihaloalkyl)alkylidene]bis-, polymer with alkanediamine (PMN P-21-67) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted, cured, or formed into an article.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3) and (7), (b), and (c). For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture or process the substance unless at a particle size of 10 microns or greater.

(iv) *Disposal.* It is a significant new use to dispose of the substance or waste streams containing the substance by incineration unless such incineration occurs at a minimum temperature of 870 degrees Celsius.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (j) are applicable to manufacturers, importers, and processors of this substance.



(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11772 Phosphonic acid, dimethyl ester, reaction products with alkyl-alkyl-alkanediol and alkanediol (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as phosphonic acid, dimethyl ester, reaction products with alkyl-alkyl-alkanediol and alkanediol (PMN P-21-93) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3) and (7), (b), and (c). For purposes of § 721.63(b), the concentration is set at 1.0%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of § 721.72(g)(1), this substance may cause: skin corrosion; serious eye damage; eye irritation; reproductive toxicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that generates a dust, mist, particulate, or aerosol that results in inhalation exposure. It is a significant new use to use the substance in consumer products where the concentration of the substance equals or exceeds 3%.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=180.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section

except as modified by this paragraph (b).

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements*. The provisions of § 721.185 apply to this section.

**§ 721.11773 Silane, halogenated (generic).**

(a) *Chemical substance and significant new uses subject to reporting*. (1) The chemical substance identified generically as silane, halogenated (PMN P-21-94) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been completely reacted (cured).

(2) The significant new uses are:

(i) *Protection in the workplace*. Requirements as specified in § 721.63(a)(3), (5), (6)(vii), (7), (8), (b), and (c). For purposes of § 721.63(b), the concentration is set at 1.0%. For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1,000.

(A) As an alternative to the respirator requirements in paragraph (a)(2)(i) of this section, a manufacture or processor may choose to follow the new chemical exposure limit (NCEL) provision listed in the TSCA Order for this substance. The NCEL is 0.05 mg/m<sup>3</sup> as an 8-hour time weighted average. Persons who wish to pursue NCELs as an alternative to § 721.63 respirator requirements may request to do so under § 721.30. Persons whose § 721.30 requests to use the NCELs approach are approved by EPA will be required to follow NCELs provisions comparable to those contained in the corresponding TSCA Order.

(B) [Reserved]

(ii) *Hazard communication*. Requirements as specified in § 721.72(a) through (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(e), the concentration is set at 1.0%. For purposes of §

721.72(g)(1), this substance may cause: skin corrosion; eye damage; specific target organ toxicity; pulmonary effects; developmental neurotoxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* It is a significant new use to use the substance other than as a deposition precursor for the manufacture of electronic components.

(iv) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=3.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i), and (k) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11774 Heteromonocycle, polymer, substituted aliphatic carbamate, [2-[(1-oxo-2-propen-1-yl)oxy]alkyl]ester (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as heteromonocycle, polymer, substituted aliphatic carbamate, [2-[(1-oxo-2-propen-1-yl)oxy]alkyl]ester (PMN P-21-115) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(vii), (7), (8), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 50 or of at least 1,000 during spray applications.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f),

(g)(1), and (5). For purposes of § 721.72(g)(1), this substance may cause: skin irritation; eye irritation; skin sensitization; respiratory sensitization. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(o).

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

#### **§ 721.11775 Alkanes, C4-8-branched and linear.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as alkanes, C4-8-branched and linear (PMN P-21-141; CAS No. 2529890-37-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3) and (7), (b), and (c). For purposes of § 721.63(b), the concentration is set at 0.1%.

(ii) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance other than for use as a transportation fuel, refinery feedstock, or fuel blending additive.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (i)

are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11776 5H-1,2-Oxathiole, 2,2-dioxide.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 5H-1,2-Oxathiole, 2,2-dioxide (PMN P-21-196; CAS No. 21806-61-1) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section. The requirements of this section do not apply to quantities of the substance after they have been incorporated into an article.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(3), (5), (6)(v) (vi), (7), (8), (b), and (c). For purposes of § 721.63(a)(5), respirators must provide a National Institute for Occupational Safety and Health (NIOSH) assigned protection factor (APF) of at least 1000. For purposes of § 721.63(b), the concentration is set at 0.1%.

(ii) *Hazard communication.* Requirements as specified in § 721.72(a) through (d), (f), (g)(1), (3)(iii), and (5). For purposes of § 721.72(g)(1), this substance may cause: carcinogenicity, reproductive toxicity, skin sensitization; respiratory sensitization; genetic toxicity; specific target organ toxicity. Alternative hazard and warning statements that meet the criteria of the Globally Harmonized System and OSHA Hazard Communication Standard may be used.

(iii) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f). It is a significant new use to process or use the substance other than an enclosed system unless the worker personal protective equipment described in paragraph (a)(2)(i) of this section is used.

(iv) *Disposal.* Requirements as specified in § 721.85(b)(1) and (2), and (c)(1) and (2). It is a significant new use to dispose of the substance by incineration unless the removal efficiency

is at least 99.9%.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (j) are applicable to manufacturers, importers, and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

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